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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PACIRA BIOSCIENCES, INC., Plaintiff, v. AMERICAN SOCIETY OF ANESTHESIOLOGISTS, INC. et al., Defendants.	Civil Action No. 21-cv-9264-MCA-JSA **Oral Argument Requested** **MOTION DAY**: July 19, 2021

PACIRA BIOSCIENCES, INC.'S RESPONSE TO DEFENDANTS' MOTION TO DISMISS WITH PREJUDICE PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(B)(6)

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INTRODUCTION

The gravamen of Defendants' motion to dismiss is that false statements, made with actual malice, which are misleading doctors and harming patients, are immune from scrutiny as long as they are published in a scientific journal—even when the Editor-in-Chief of that journal is himself guilty of the same misconduct. Defendants are wrong. There is no categorical exception inoculating false or misleading statements simply because they are published in a journal or made by a scientist or physician. To the contrary, as Defendants' own cases make clear, such statements constitute trade libel when they make "false statement[s] … denigrating the quality of a business' goods or services," "misportray facts," "imply that undisclosed facts also exist supporting the authors' conclusions," or present as "unassailable fact" that which is only "debatable hypothes[i]s." *Ony, Inc. v. Cornerstone Therapeutics, Inc*., 2012 WL 1835671, at *7-10 (W.D.N.Y. May 18, 2012) (citation omitted).

Pacira has alleged that Defendants' statements are actionable for just such reasons. Over the course of a series of high profile articles, Continuing Medical Education ("CME") content, and a related podcast, Defendants repeatedly and categorically claimed that Pacira's principal product—EXPAREL or liposomal bupivacaine—is "not superior" to non-liposomal bupivacaine, and instead provides "inferior analgesia" (or pain relief) compared to local anesthetics. Compl. ¶¶ 60, 69.

Such statements do not purport to share opinions; rather, they purport to present *facts*.

As Pacira has explained, however, those claims are false, or at minimum, highly misleading. EXPAREL *is* superior—indisputably so—compared to local anesthetics in its ability to deliver prolonged pain relief. And although Defendants imply that reliable studies about EXPAREL suggest it does not provide clinically significant benefits relative to alternatives, in fact the balance of studies concludes the opposite. Importantly, moreover, EXPAREL's long-acting pain relief can reduce or eliminate the need for physicians to treat certain post-surgical patients with opioids—a critical and meaningful clinical goal given the magnitude of America's horrific and ongoing opioid crisis. At minimum, even Defendants' own stilted and biased results rebuff Defendants' false claim that EXPAREL offers *inferior* pain relief. *See, e.g.*, Compl. Ex. 1 at 1 (Hussain Article) (conceding that EXPAREL is correlated with a statistically significant reduction in reported pain relative to local anesthesia).

Other claims made across Defendants' articles, CME content, and podcasts are equally false or misleading—affirmatively misrepresenting Defendants' own conflicts of interest, falsely implying that industry-sponsored trials are inherently biased or unreliable, and mischaracterizing key facts to misrepresent the robustness of their own methodology and conclusions. *See, e.g.*, Compl. ¶¶ 36-67. Here again,

Pacira has explained that Defendants' false and misleading statements are egregious deviations from scientific norms—errors so substantial that they can be explained only by an intent to reach preconceived results, advance a pro-opioid agenda, and disparage EXPAREL at the expense of the truth. *Id.*

Defendants may argue otherwise. But the question at issue now is not whether Pacira can *prove* its claims—but only whether it has met its burden to *plead* them. It has. At this early stage of the case, where the "allegations in the pleadings must be accepted as true and [Pacira] must be given the benefit of every favorable inference that can be drawn from those allegations," *Kessler Inst. for Rehabilitation, Inc. v. Mayor of Essex Fells*, 876 F. Supp. 641, 662 (D.N.J. 1995), Pacira has adequately alleged that Defendants made or implied factual claims that are false and did so with actual malice. It need do no more.

Early on in this case, Defendants claimed they were eager to have this Court reach the merits of Pacira's claims on a fully developed record. To that end, they urged this Court to approve expedited discovery so that Defendants could prove that their assertions about EXPAREL were accurate and justified at summary judgment. *See, e.g.*, May 7, 2021 Hr'g Tr. 36:13-15 ("[W]e'd like to take our discovery on the entire case … in an expedited fashion …."); *id.* at 18:2-7 ("I want to take expedited discovery, because I want to move for summary judgment."). But once confronted with discovery that threatened to confirm Pacira's allegations and expose

Defendants' pro-opioid agenda, Defendants quickly changed their tune, urging this Court to stay discovery and cut off any inquiry into the merits of Pacira's claims.

Remarkably, Defendants accuse Pacira of trying to "stifle[] the … right to scientific debate." Mem. in Supp. of Mot. to Dismiss 4 ("Motion"), Dkt. 58-1. In truth, however, it is *Defendants* who are guilty of that charge. As Pacira has explained, it is Defendants who have refused to afford those who disagree with them an equivalent platform to present their contrary views. Compl. ¶ 33. And it is Defendants who now urge this Court to avoid exposing their factual claims and motives to the crucible of discovery.

This Court should reject Defendants' attempt to avoid any meaningful scrutiny of their statements, which threaten not only to cause pecuniary harm to Pacira, but to mislead physicians and put patients at risk. EXPAREL offers a long-lasting, non-opioid, non-narcotic pain medication to treat post-surgical pain. *Id.* ¶ 25. It is a crucial tool that countless physicians use to provide essential pain relief while reducing, and in some cases eliminating, the need to use opioids to treat a patient's pain. By making false and misleading statements designed to discourage physicians from using EXPAREL, Defendants not only are causing pecuniary harm to Pacira, but misleading physicians and placing patients at risk of exposure to greater post-surgical pain and greater exposure to opioids. Pacira is entitled to defend its product—which is central to its mission to provide non-opioid pain

management—from Defendants' false and disparaging statements. Defendants' motion to dismiss should be denied.

STATEMENT OF FACTS

A. Pacira and EXPAREL

1. EXPAREL and the Opioid Crisis

As Pacira explained in its complaint, the opioid crisis facing the United States in unparalleled. Compl. ¶ 24 (citing report from the President's Commission on Combating Drug Addiction and the Opioid Crisis). Americans consume and produce more opioids than any other country in the world. *Id.* According to the U.S. Centers for Disease Control and Prevention ("CDC"), the number of opioid overdoses has quadrupled since 1999. *Id.* Unsurprisingly, opioid prescriptions quadrupled during this period as well, triggering the present crisis. *Id.* In 2015, the amount of opioids prescribed in the United States was enough for every American to be medicated around the clock for three weeks. *Id.* In that same year, nearly two-thirds of drug overdoses were linked to opioids, especially Percocet, OxyContin, heroin, and fentanyl. *Id.*

The opioid epidemic is not one that began on a street corner: in many cases, it began in doctors' offices and hospitals. *Id.* Evidence indicates, moreover, that certain opioid producers have been an instrumental cause of this epidemic, aggressively marketing their products to encourage their use, including by downplaying the addictive qualities of opioids. President's Commission on

Combating Drug Addiction and the Opioid Crisis at 20 (Nov. 1, 2017), https://www.hsdl.org/?view&did=805384 (identifying the "opioid pharmaceutical manufacturing and supply chain industry" as a "contributor[] to the current crisis"). To further promote their product, opioid manufacturers sponsor educational events and CME activities—one such company "sponsored over 20,000 educational events for physicians and others on managing pain with opioids, claiming their potential for addiction was low." *Id.* The President's Commission on Combating Drug Addiction and the Opioid Crisis has also recognized that "[t]o this day, the opioid pharmaceutical industry influences the nation's response to the [opioid] crisis," including by opposing CDC guidelines cautioning against the over-prescription of opioids. *Id.* at 20-21. Addressing the opioid epidemic must involve changes to the way physicians treat and manage patient pain. Compl. ¶ 25. To do so, alternatives to opioid pain medications are required.

That is where Pacira and EXPAREL come in. Pacira is a pharmaceutical company and a leading provider of non-opioid pain management. *Id.* Pacira's corporate mission is to provide a non-opioid pain management option to patients. *Id.* Pacira is the manufacturer of the drug EXPAREL, the brand name for the sole liposomal bupivacaine product approved for sale in the United States. *Id.* Bupivacaine is a non-opioid, non-narcotic local anesthetic. *Id.* For surgical patients, it is either injected directly into the area near the surgical site to numb the area or

injected into the primary nerves that run to the surgical area. *Liposomal* bupivacaine (i.e., EXPAREL), contains specially formulated bupivacaine encapsulated in liposomal chambers, designed to release into the body over a prolonged period of time as the chamber walls break down. *Id.* ¶ 26. As a result, EXPAREL is able to release analgesics into the body over a prolonged period of time, providing longer-lasting pain relief than generic bupivacaine. *Id.* Whereas bupivacaine provides pain relief for eight hours, or up to 12 hours when combined with epinephrine, EXPAREL is clinically proven to provide relief for up to seventy-two hours.[1] As a result, patients should need fewer doses of other pain medications, especially opioids, after surgery. *Id.*

EXPAREL is approved for treatment of postsurgical pain. In 2011, the FDA approved EXPAREL for single-dose infiltration into the surgical site to produce postsurgical local analgesia, and in March 2021, this indication was extended to pediatric use. *Id.* ¶ 27. In 2018, the FDA approved EXPAREL as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. *Id.* Pacira

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[1] *See* Stephen R. Gorfine et al., *Bupivacaine Extended-Release Liposome Injection for Prolonged Postsurgical Analgesia in Patients Undergoing Hemorrhoidectomy: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial*, 54 Diseases of Colon & Rectum 1552-1559 (Dec. 2011), https://pubmed.ncbi.nlm.nih.gov/22067185/. This is one of the pivotal studies on which the FDA relied in approving EXPAREL. *See* FDA, EXPAREL (Apr. 2018), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022496s9lbl.pdf.

sells EXPAREL to the Department of Defense, hospitals, ambulatory surgical centers, and healthcare providers all over the country. *Id.* ¶ 28. To date, over 8 million patients have been treated with EXPAREL. *Id.* ¶ 27.

2. EXPAREL Is an Effective Analgesic

EXPAREL is an effective and important treatment option available to reduce the use of opioids in surgical patients, especially patients undergoing procedures likely to cause severe pain that lasts more than 24 hours. Dkt. 3-4 at 4 (DiGiorgi Rep.). Not only has the FDA approved use of EXPAREL, but the federal Centers for Medicare and Medicaid Services ("CMS") has also recognized its efficacy. *Id.* at 5. CMS reviewed studies of EXPAREL and other non-opioid pain treatments and, based on those studies, determined that it would pay separately for use of EXPAREL at ambulatory surgical centers, but not any other non-opioid pain medication. *Id.* CMS concluded that, unlike for EXPAREL, it "ha[s] not found compelling evidence for other non-opioid pain management drugs described above to warrant separate payment at this time." 83 Fed. Reg. 58,818, 59,069 (Nov. 21, 2018). Similarly, multiple professional medical societies recognize the benefit that EXPAREL offers patients and either recommend its use or recommend that its members be familiar with EXPAREL, including the American Pain Society and the American Society of Regional Anesthesia and Pain Medicine, among others. *See* DiGiorgi Rep. at 5-6 (surveying professional society guidelines).

EXPAREL has a strong following for a reason: it has been studied extensively, and the studies demonstrate that when EXPAREL is used properly and for the right procedures, it is an effective means of providing long-lasting post-operative, non-opioid pain relief. In total, over 150 primary research studies (randomized, controlled trials and observational studies) have been published to date that evaluate the use of EXPAREL compared to an alternate local anesthesia. *Id.* at 27, app. I. The studies on balance are favorable to EXPAREL. *Id*. at 2-7. For example, a randomized-control trial presented in 2015 found that patients receiving EXPAREL consumed *50% fewer* opioids than patients who received only opioids, had improved pain scores, and fewer opioid-related side effects. *Id.* at 7 (discussing Yalmachnili trial).

Other studies also show a significant benefit for patients when compared to traditional (non-liposomal) bupivacaine alone. For example, a PILLAR trial randomized 139 subjects undergoing total knee replacements into two groups: an experimental group receiving both non-liposomal bupivacaine and EXPAREL (for immediate release and extended release), and a control group receiving only non-liposomal bupivacaine. *Id.* at 8. The results indicated that EXPAREL offered substantial benefits in comparison to non-lipsomal bupivcaine. The experimental group had much better pain scores and their average opioid consumption in the first 48 hours was only 16 mg compared to 80 mg for the control group. *Id*. (discussing

Mont trial reported in 2018). Similarly, the Mayo Clinic in Rochester, Minnesota conducted a large retrospective study of 358 patients to compare local infiltration of EXPAREL to bupivacaine alone. *Id.* at 9. The EXPAREL group obtained comparable pain scores to alternative analgesics but required fewer opioids and had fewer opioid-related side effects. *Id.* (discussing trial reported in 2016).

However, the benefit EXPAREL provides depends on several factors: the surgical procedure for which it is used (e.g., rotator cuff surgery, knee replacement surgery, bunion surgery, etc.), how EXPAREL is used (i.e., direct infiltration versus peripheral nerve block), the dose, and proper technique / implementation by the surgeon or anesthesiologist. *Id.* EXPAREL does not provide much benefit over other options to patients undergoing treatments that do not have serious pain lasting more than 24 hours—traditional local anesthetics work just fine for controlling pain in those circumstances. *Id*. at 4 (explaining that EXPAREL provides more benefit for certain surgical procedures and types of use than others); *see also* Dkt. 3-8 ¶¶ 2, 4 (Kreger Decl.) (discussing his success in treating patients with EXPAREL, but acknowledging that there are different uses of EXPAREL, some of which are uncommon). For this reason, to evaluate the effectiveness of EXPAREL, it is critical to compare studies that relate to the same types of surgical procedures.

B. The ASA and Anesthesiology

The ASA is a professional medical association centered on the practice of anesthesiology. Compl. ¶ 5. The ASA's membership is open to anesthesiologists, as well as anesthesiologist assistants and scientists interested in anesthesiology; other non-physicians who nevertheless provide anesthesia care may join as educational members. *Id.* ¶ 6. The ASA has over 54,000 members, including members located in New Jersey. *Id.*

The ASA publishes a peer-reviewed medical journal, *Anesthesiology* (the "Journal"). *Id.* ¶ 7. The ASA boasts that it "lead[s] the world in publishing and disseminating the highest quality work to inform daily clinical practice and transform the practice of medicine in the specialty." *Id.* ¶ 29. The Journal publishes 12 issues a year and is available in both print and online forms. *Id.* ¶ 30. The ASA provides free online access to certain highlighted articles, and free access to many previously published articles. *Id.* A subscription is included as a free benefit for Society members, but subscriptions are also available to any individual and institutions for a fee. *Id.* The Journal has approximately 51,502 subscribers in total, including 43,332 print subscribers, and 8,170 online subscribers. The website receives, on average, 422,964 visits per month. *Id.*

The current Editor-in-Chief of the Journal, Dr. Evan Kharasch, has previously published multiple articles critical of non-opioid pain medications like EXPAREL

and in favor of the use of opioids, including articles published in *Anesthesiology* itself. *Id.* ¶ 31. For example, Dr. Kharasch authored an editorial in an April 2020 issue of *Anesthesiology* in which he described using non-opioid drugs like EXPAREL as an "arbitrary and commercially influenced" approach to management of postoperative pain, that "presently lack[s] compelling evidence." *Id.* & n.23. Asking whether "the elimination of intraoperative opioid use [is] a reasonable goal," Kharasch wrote that "[w]e appear poised to fundamentally change anesthesia practice without having a rational basis for doing so." *Id.* & n.24. Kharasch's own research interests include studies supporting opioid use in post-surgery patients. *Id.* & n.25. He has also received millions of dollars in federal funding for opioid-related research and has publicly advocated for opioids, *see* Dkt. 3-5 at 6 (Mehlman Decl.), but states on the Journal's website that he has no conflicts of interest.[2] As Editor-in-Chief, Kharasch has final say over the content published in each issue, and appears to be using his position to advance his pro-opioid agenda and disparage competitive alternatives like EXPAREL. Compl. ¶ 31.

[2] ASA Publ'ns, Editorial Board, https://pubs.asahq.org/anesthesiology/pages/editorial-board#Kharasch (last visited July 5, 2021).

C. Defendants Disparage Liposomal Bupivacaine

The February 2021 issue of *Anesthesiology* focuses on EXPAREL, with multiple articles and the Journal cover dedicated to the product.[3] *See* Compl. Ex. 7, Feb. 2021 *Anesthesiology* cover page. Rather than attempt to provide a fair and balanced assessment of EXPAREL, the Journal presents only an anti-EXPAREL view, spouting significant false and misleading claims, while packaging them as though they were conclusions derived from rigorous scientific analysis (they were not). The cover of the issue states that "Liposomal Bupivacaine Is Not Superior to Standard Local Anesthetics," with no accompanying qualifying or explanatory information. *Id.* The issue also contains three articles, each of which parrots the same false statements broadcast on the Journal's cover:

1. A purported systematic review and meta-analysis, titled *Perineural Liposomal Bupivacaine Is Not Superior to Nonliposomal Bupivacaine for Peripheral Nerve Block Analgesia: A Systematic Review and Meta-Analysis* by Defendants Nasir Hussain, Richard Brull, Brendan Sheehy, Michael K. Essandoh, David L. Stahl, Tristan E. Weaver, and Faraj W. Abdallah (**"Hussain Article"**). *See* Compl. Ex. 1.

2. A subjective "narrative review," titled *Clinical Effectiveness of Liposomal Bupivacaine Administered by Infiltration or Peripheral Nerve Block to Treat Postoperative Pain: A Narrative Review*, by Defendants Brian M. Ilfeld, James C. Eisenach, and Rodney A. Gabriel (**"Ilfeld Review"**). *See* Compl. Ex. 2.

[3] ASA Publ'ns, Anesthesiology: Volume 134, Issue 2 (Feb. 2021), https://pubs.asahq.org/anesthesiology/issue/134/2.

3. A guest editorial by Dr. Mary Ellen McCann, titled *Liposomal Bupivacaine: Effective, Cost-effective, or (Just) Costly* (**"McCann Editorial"**). *See* Compl. Ex. 3.

All three articles make the same blanket misstatements about EXPAREL's efficacy. Compl. ¶¶ 36, 38. The title of the Hussain Article prominently displays the authors' conclusion that EXPAREL "is *not superior* to nonliposomal bupivacaine for peripheral nerve block analgesia." Hussain Article at 1 (emphasis added). Similarly, the Ilfeld Review states in its abstract that "[t]he preponderance of evidence fails to support the routine use of liposomal bupivacaine over standard local anesthetics." Ilfeld Review at 1. These inaccurate conclusions ignore that EXPAREL's efficacy depends on the specific surgical procedure and EXPAREL's method of use. Compl. ¶ 38. Those two articles are also replete with substantial methodological failings and misstatements. *Id.* ¶¶ 37-40. Additionally, two authors of the Ilfeld Review, Ilfeld and Gabriel, failed to disclose that they had received payments from Pacira's competitors, Heron Therapeutics and InfuTronix. Compl. ¶¶ 49-52. Dr. McCann repeats the misleading findings of both the Hussain Article and Ilfeld Review. Compl. Ex. 3, McCann Editorial at 141; *see also* Compl. ¶¶ 54-56.

Despite the problems with these articles, the Journal, through the leadership of Dr. Kharasch, chose to highlight them and their false conclusions as teaching material in their accredited CME materials and as the subject of a podcast. Compl.

¶¶ 59, 65. Like many medical journals, *Anesthesiology* offers a "journal club," in which the Journal highlights certain of its articles and develops CME questions from those articles. *Id.* ¶ 59. For a fee, subscribers can access the questions online and receive credit to satisfy medical licensure requirements. *Id.* The February CME materials drew questions from the Hussain and Ilfeld articles, and presented as fact the misleading and false statements in the articles. *See* Compl. Ex. 4, ASA Journal CME Posttest. The materials also exhibited commercial bias in violation of industry standards for CME materials. *Id.* ¶¶ 59-64. The ASA also publishes a podcast on its website accompanying each issue of *Anesthesiology*. *See* Compl. Ex. 5, Anesthesiology Podcast Tr. The February 2021 podcast discussed the conclusions of both the meta-analysis and the narrative review regarding liposomal bupivacaine, without acknowledging their flaws. *Id.* Like the challenged CME activity, the podcast restated many of the false statements contained in the challenged articles, spreading misleading information from the February 2021 articles to an audience beyond the issue's readers. *See id.*

Pacira has now lost business as a result of the Articles. Compl. ¶ 70; Dkt. 3-9 ¶¶ 2-3 (Sherrod Decl.). Moreover, Pacira's competitors—at least one of whom financially supported Ilfeld and Gabriel—are now capitalizing on the articles in their own advertising and publications, ensuring that Pacira will continue to suffer harm. Compl. ¶¶ 71-73.

ARGUMENT

I. LEGAL STANDARD

In order to survive a motion to dismiss, a plaintiff must provide "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). While this standard requires the plaintiff to show "more than a sheer possibility that a defendant has acted unlawfully," this standard is not a "probability requirement." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The court should take all well-pleaded factual allegations as true, and then "determine whether they plausibly give rise to an entitlement to relief." *Bistrian v. Levi*, 696 F.3d 352, 365 (3d Cir. 2012) (citation omitted). A claim is facially plausible when there are sufficient facts from which to draw a "reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. When deciding a motion to dismiss under Rule 12(b)(6), the court should generally only consider the complaint and its attached exhibits. *Angstadt v. Midd-West Sch. Dist.*, 377 F.3d 338, 342 (3d Cir. 2004).

To assert a trade libel claim under New Jersey law, a plaintiff must demonstrate: (1) publication (2) of false allegations concerning plaintiff's property, product, or business, (3) with malice, and (4) special damages. *See Mayflower Transit, LLC v. Prince*, 314 F. Supp. 2d 362, 378 (D.N.J. 2004). The derogatory publication must be "of a kind calculated to prevent others from dealing with him,

or otherwise to interfere with [plaintiff's] relations with others." *Patel v. Soriano*, 848 A.2d 803, 835 (N.J. Super. Ct. App. Div. 2004). As explained below, Pacira has sufficiently alleged each element of its trade libel claim.

II. PACIRA HAS SUFFICIENTLY ALLEGED ACTIONABLE FALSE STATEMENTS

Defendants do not appear to dispute that the statements Pacira identifies as false could be construed as defamatory, because statements stating or implying that liposomal bupivacaine is not an effective product could certainly "prevent others from dealing with" Pacira or its product EXPAREL. Instead, Defendants raise essentially two arguments. First, they claim that their statements are pure opinions that are not actionable. Second, Defendants claim that their statements are not actionable, no matter how false or derogatory, because they constitute "science." Neither defense is persuasive.

In order to be actionable as trade libel, the truth or falsity of a statement must be "verif[iable]"; as a result a statement of pure opinion that cannot be tested or proven false generally is not actionable. *See Wolfe v. Gooding & Co.*, 2017 WL 3977920, at *3 (D.N.J. Sept. 11, 2017); *see also Mangan v. Corp. Synergies Grp., Inc.*, 834 F. Supp. 2d 199, 205 (D.N.J. 2011) ("Statements of pure opinion do not satisfy this requirement because such statements only 'reflect a state of mind,' and therefore generally 'cannot be proved true or false.'" (citation omitted)). Even statements of opinion, however, may be actionable "when they imply false

underlying objective facts." *Mayflower Transit*, 314 F. Supp. 2d at 372; *see also Wolfe*, 2017 WL 3977920, at *3. "The higher the 'fact content' of a statement, the more likely that the statement will be actionable." *Ward v. Zelikovsky*, 643 A.2d 972, 979-80 (N.J. 1994) (citation omitted).

This case is not about a challenge to pure opinions. Here, the three challenged articles state or imply false underlying *facts*, which ASA then endorsed and elevated in importance by disseminating them to an even broader audience through its podcast and CME materials. ASA's own CME materials underscore the point—by inviting physicians to answer whether it is "true" or "false" that EXPAREL provides inferior analgesia compared to local anesthetics, ASA affirms that the statements in question are claims of fact, the truth of which can be verified, not statements of pure opinion.

Defendants' own case law demonstrates that factual statements, such as the claims Pacira challenges, are actionable. *See* Mot. at 14 ("*Absent falsification or misstatement of underlying data*, such disputes over the conclusions to be drawn are not actionable …." (emphasis added)); *ONY*, 2012 WL 1835671, at *10 (dismissing claim where challenged article "reflects the facts on which the authors' conclusions are based, *and does not imply that undisclosed facts also exist supporting the authors' conclusions*" (emphases added)); *see also Biolase, Inc. v. Fotona Proizvodnja Optoelektronskih Naprav D.D.*, 2014 WL 12579802, at *5 (C.D. Cal. June 4, 2014); *Joseph v. Springer Nature*, 2021 WL 1372952, at *7 (S.D.N.Y. Apr.

12, 2021), *appeal filed*, No. 21-959 (2d Cir. Apr. 15, 2021). As discussed below, Pacira has identified myriad ways in which the challenged materials present verifiably inaccurate or false descriptions of the data on which the studies rely.

A. The Hussain Article Made False Statements About EXPAREL

For example, Pacira alleged that both the Hussain article and the cover of the February 2021 issue of *Anesthesiology* make the blanket statement that liposomal bupivacaine is "not superior" to standard analgesics, with no qualifying language, claiming (or implying) that EXPAREL is not superior to other analgesics in any circumstance. That claim is simply untrue.

There is strong evidence that patients who receive a single administration of EXPAREL experience pain relief for as long as 72 hours. DiGiorgi Rep. at 3. In contrast, no study has ever found that a single administration of bupivacaine (or a similar drug, ropivacaine) provides pain relief past *10 hours*. *Id.* at 10.[4] It is *simply impossible* for another local anesthetic to provide pain relief as long as EXPAREL without multiple doses and/or use of other pain medications. *Id.* In addition, as discussed *supra* p. 9, over 150 primary research studies have been conducted

[4] Indeed, Hussain has authored a prior paper conceding that EXPAREL works up to 24 hours. *See* Nasir Hussain et al., *The Mornings After—Periarticular Liposomal Bupivacaine Infiltration Does Not Improve Analgesic Outcomes Beyond 24 Hours Following Total Knee Arthroplasty: A Systemic Review and Meta-Analysis*, 46 *Regional Anesthesia & Pain Medicine* 61, 61-72 (2021), https://rapm.bmj.com/content/46/1/61.

comparing EXPAREL to an alternative local anesthesia, and the results have favored EXPAREL. DiGiorgi Rep. at 7. Other studies comparing EXPAREL to non-liposomal bupivacaine have demonstrated that patients taking EXPAREL needed fewer opioids following surgery, and had comparable or better pain scores. *Id.* at 8-9; *supra* pp. 8-10. Thus, it is wrong to say that EXPAREL "is not superior" to local anesthetics.

Indeed, the *Article's editor* concluded only that the results of the meta-analysis were "unclear." Hussain Article at 1. It is standard practice to conclude that results are "inconclusive" based on data and results like those presented in the Hussain Article. The ASA itself only concludes that literature is "equivocal" if a meta-analysis does not find "significant differences … among groups or conditions."[5] Yet despite these standards, the editor's conclusion, and the wealth of studies indicating that EXPAREL *is* more effective than standard analgesics in many respects—the authors took it upon themselves to state, unequivocally, that EXPAREL is "not superior." This statement is demonstrably false.

In addition, the authors of the Hussain Article fail to disclose that the underlying studies they reviewed were limited to specific procedures, and that the

[5] *Practice Guidelines for Acute Pain Management in the Perioperative Setting*, 116 Anesthesiology 248, 250 (Feb. 2012), https://doi.org/10.1097/ALN.0b013e31823c1030.

benefits of EXPAREL depend, in part, on the surgical procedure for which it is used. Compl. ¶¶ 35, 38; DiGiorgi Rep. at 7-9. They likewise fail to disclose that there are certain procedures for which studies overwhelmingly demonstrate the effectiveness of EXPAREL. DiGiorgi Rep. at 7-9. The authors purport to review the relevant universe of data, while omitting—seemingly intentionally—critical data on EXPAREL's efficacy. Compl. ¶¶ 38-39, 41. More generally, the Hussain Article stated that it included studies that meet certain criteria. Hussain Article at 2. In fact, the authors cherry-picked studies to include, excluding favorable studies that nevertheless fit the authors' criteria for inclusion, and including several unfavorable studies that did not meet their criteria. Compl. ¶¶ 38, 39, 41; *see also* DiGiorgi Rep. at 12-13 & n.42; Dkt. 3-3 at 12-13 (Trikalinos Rep.). The article does not disclose this, much less provide a reason why. Even the authors' highly curated studies, however, indicate that EXPAREL provides a "statistically significant" *improvement* in post-operative pain scores compared with local anesthetics, facts incompatible with the article's unequivocal statement that EXPAREL is "not superior." Hussain Article at 1.

The Article also falsely claimed that "all estimates" of the effect of EXPAREL "were of high quality and characterized by low levels of heterogeneity," which the authors claimed "strengthen[ed] the internal validity of this review." Hussain Article at 12. In order to determine whether study outcomes are sufficiently similar for

comparison, it is standard procedure for scientists to calculate "statistical heterogeneity," with low heterogeneity indicating that the studies are comparable, and higher heterogeneity indicating that the studies are less comparable, and the conclusions to be drawn from comparing such studies less reliable. Compl. ¶ 43; *see also* Trikalinos Rep. at 20-21; DiGiorgi Rep. at 13-14 n.51. As Dr. Trikalinos explained in his expert report, the authors' statements that the studies exhibited "low levels of heterogeneity" is false. In fact, the authors never tested for heterogeneity for pain scores—the primary outcome examined—and yet *still advised their readers that the heterogeneity was low*. *See* Hussain Article at 10. Dr. Trikalinos found that the statistical heterogeneity of the trials reviewed in the article is 83%, far more than the 50% threshold the authors identified as constituting "significant heterogeneity." Hussain Article at 4; Trikalinos Rep. at 20. Indeed, the vast majority of efforts by other researchers to meta-analyze EXPAREL research have resulted in inconclusive or neutral results due, in part, to statistical heterogeneity of the relevant studies. *See* DiGiorgi Rep. at 15-16 (Table 3) (surveying available meta-analyses).

The authors also chose to use certain methodologies that significantly depart from industry standards, and which appear to be designed to arrive at a pre-determined outcome. Among other things, the authors:

- Use a method called "crude pooling," rather than the correct "stratified pooling" method. Compl. ¶ 42. This approach destroys randomization; ignores stratification; and masks myriad differences in trials, including the types of procedures, the relative pain involved, the

dosage levels, the way EXPAREL was used, and additional pain treatments provided. Trikalinos Rep. at 9-10. Indeed, Dr. Trikalinos described this widely rejected method as a lesson in "how *not to do a meta-analysis*," and that he cannot recall a publication that employed this method in the past 20 years. *Id.* at 10.

- Apply a "correction" to account for the possibility that an outcome was due simply to chance (called the "Bonferroni-Holm" correction), when such a correction is not appropriate in a meta-analysis, and applying the correction strongly suggests that they were deliberately seeking to minimize any difference between EXPAREL and the comparators. *Id.* at 13.

- Employ a confidence interval that is far more strict than is commonly used (99% versus the standard 95%), thus arbitrarily requiring EXPAREL to achieve a higher-than-normal statistical threshold to establish its efficacy, indicating that they were seeking to diminish the benefit of EXPAREL. *Id.*

The authors also committed a series of other errors, including:

- Omitting important data, including all trial-level numerical information—contrary to industry practice—preventing replication or testing of the authors' work. *Id.* at 14.

- Deliberately choosing an inaccurate method to determine how much weight to give each trial. Each trial is not given equal value in a meta-analysis; the proper method is a system called inverse-variance, in which trials with the lowest variance (i.e., the least uncertainty in the results) receive the greatest weight. Trikalinos Rep. at 5-6. Curiously, the authors use the correct method for their secondary outcomes (i.e., the results they derived that were of secondary importance, such as the level of opioid consumption), but then inexplicably choose to use a different—and less accurate—system for their primary outcome (assessing pain scores). *Id*. at 11.

- Ignoring correlations between successive pain measurements in the same patients. *Id*. at 11-12. In other words, the authors look at pain measurements across all study subjects at the 24-hour, 48-hour, and 72-hour post-operative periods as if they were independent, without

considering that individual patients' pain scores at each interval are likely correlated (e.g., a person with low pain scores at 24 hours may have low pain scores at 48 and 72 hours). *Id*. Failing to account for correlations can change the variances, which can affect the weights in the meta-analysis and confidence intervals of the meta-analysis means. *Id*. at 12.

- Attempting to impute the standard deviation used in the underlying trials when it was not available in the manuscript. *Id.* This inherently introduces uncertainty and the risk of error. *Id*.

Discovery will show that the Hussain article is riddled with errors, omissions, and misstatements, which underlie its damaging and inaccurate conclusion that EXPAREL is "not superior" to standard analgesics.

B. The Ilfeld Review Made False Statements About EXPAREL

The Ilfeld Review suffers from similar problems, again repeating the overbroad factual conclusion that liposomal bupivacaine is "not superior" to other anesthetics. Compl. ¶ 38. Again, studies show that this is inaccurate: EXPAREL *is* superior to local anesthetics, or standard bupivacaine, when used properly in appropriate procedures. *See supra* pp. 8-10, 19-20.

Like the Hussain Article, the Ilfeld Article misrepresents the accuracy of its conclusions and the underlying studies it relies on. Again, the authors purport to review the data relevant to EXPAREL, but never discuss the most relevant group of studies. Most critically, the authors chose to exclude the most relevant anesthesia procedure in what purports to be a "narrative" review—a review of the literature on EXPAREL. Compl. ¶ 47. While the article discusses the studies of random

anesthesia procedures, it never discusses studies of single administration of EXPAREL versus continuous infiltration of a local anesthetic. DiGiorgi Rep. at 23-24. Continuous infiltration of a local anesthetic is the most comparable alternative to EXPAREL, because it most closely mimics EXPAREL's intended "extended-release" function. *Id.* In other words, the authors intentionally chose to discuss the trials comparing apples to oranges, but never discussed the trials comparing apples to apples. Studies that make the apples to apples comparison show that EXPAREL is beneficial over the comparator, resulting in significantly reduced opioid consumption. *Id.* (summarizing relevant studies).

At the same time, the authors rely on pretexts to dismiss evidence that supports EXPAREL and refutes the article's false conclusion. For example, in addition to dismissing industry-funded trials, the authors criticize two pivotal placebo studies and the PILLAR study for using a "single imputation" method as a means to account for rescue analgesics the patients were provided. Ilfeld Review at 285, 290 (citation omitted). That criticism is wrong,[6] but regardless, the trials the Ilfeld Review assesses *make no effort at all to account for the additional analgesics*. DiGiorgi Rep. at 18. Thus, while the authors argue that there are more accurate methods to

[6] The placebo studies did not use a single-imputation method, they used a combination method. DiGiorgi Rep. at 19. And that method was also the common and FDA-accepted method at the time. Indeed, the lead author, Ilfeld, used that very method in an EXPAREL study. *Id.* at 20.

account for rescue analgesics, the authors choose to be silent on the fact that the trials they champion were far worse.

In addition, the authors "do not tell the truth about the biases and problems with studies that are not favorable to EXPAREL." Compl. ¶ 47. The article criticizes studies supporting EXPAREL but hide the substantial problems of many of the studies that do not support EXPAREL. *Id.* ¶ 48. Dr. DiGiorgi performed a proper bias-risk assessment using the Cochrane framework, and determined that *11 studies* that the Ilfeld Review authors stated had a low risk of bias or simply "some concerns," actually suffer from substantial risk of bias. *Id*. at 22-23 (Table 4). The authors conceal those weaknesses.

Finally, two of the authors of this study, Ilfeld and Gabriel, failed to disclose payments they received from Pacira's competitors, in violation of standard medical ethics. Compl. ¶¶ 49-53. Tellingly, Ilfeld's omitted disclosures were included in other, recently published studies, but omitted here. *Id.* ¶ 52 & nn.33-35. ASA argues that the failure to report disclosure payments is irrelevant because the financial disclosure statements are not about EXPAREL, but the incorrect disclosures contribute to the misleading impression created by the article. Mot. at 27. The article gives the impression that it is an unbiased analysis of the effectiveness of EXPAREL, when, in fact, the authors had a financial interest in the outcome of the study.

In short, the authors falsely imply that a comprehensive and unbiased review of the most relevant EXPAREL studies indicates that EXPAREL is not superior to other analgesics, when the most relevant studies show otherwise and several of the authors hid conflicts of interest. Here again, taking Pacira's allegations as true—as this Court must at the pleading stage—Pacira has validly alleged the existence of statements that can (and will) be proven false with the benefit of discovery.

C. The CME Materials, McCann Editorial and Podcast Contain False Statements About EXPAREL

Finally, the CME materials, McCann Editorial, and podcast contain or repeat many of the same false statements about EXPAREL. The CME materials restate as fact the flawed and misleading conclusions of the articles, including the misleading statement that EXPAREL is "not superior" to other anesthetics. Compl. ¶¶ 59, 62-64. For example, the second question asks, "Which of the following is true regarding studies comparing liposomal bupivacaine to aqueous local anesthetics?" Compl. Ex. 4 at 2-3. The "correct" answer is given as "all of the above," including Choice B, which says that a high percentage of randomized control trials showed that infiltration of the surgical site with liposomal bupivacaine provides inferior analgesia to a peripheral nerve block with local anesthetics. *Id.* This is inaccurate: studies that have compared EXPAREL infiltration to peripheral nerve blockade have shown statistically significant findings in favor of EXPAREL, and certainly did not

demonstrate that EXPAREL was *inferior* to alternatives. Compl. ¶ 60; *see also* Hussain Article at 1.

In addition, the first questions states, true or false: "A majority of the studies reporting lower postoperative pain scores or lower opioid usage with liposomal bupivacaine compared with aqueous local anesthetic or placebo were deemed to be at high risk for bias (i.e., industry sponsored)." *See* Compl. Ex. 4 at 1. The materials state the answer is true, that the majority of studies had a high risk for bias. *Id.* But the question misleads the reader by equating industry sponsorship with risk of bias, when in fact, industry standards for assessing bias do not consider industry sponsorship as relevant to measuring bias. Compl. ¶ 61. The statement is therefore false. A true/false statement is a verifiable statement of fact by definition.

By promoting the Defendants' unfounded bias against EXPAREL, the CME questions also violate industry standards related to CME activities, which require the material to be "fair and balanced," without commercial bias. *Id.* ¶¶ 62-63. These standards also require providers to disclose any conflicts of interest. *Id.* ¶ 63. The CME activities are in violation of these standards, yet give the impression that the facts they present are accurate and supported by scientific study, when that is not the case.

The McCann Editorial parrots many of the same false conclusions found in the Hussain and Ilfeld articles. *Id.* ¶ 54. McCann also goes further, implying that

Pacira aggressively markets EXPAREL to line its pockets, even though it allegedly is not "an improvement over existing, inexpensive drugs." McCann Editorial at 141; *see also* Compl. ¶¶ 55-56. The Editorial strongly implies that the FDA approved EXPAREL with insufficient evidence, and that customers purchase EXPAREL only because of Pacira's marketing strategy. Compl. ¶ 55. However, EXPAREL's effectiveness is demonstrated by countless studies and by the fact that licensed physicians have chosen to use EXPAREL in novel ways, beyond the methods for which Pacira markets it. *Id.* Customers use EXPAREL because it works.

Finally, the podcast produced in connection with the February 2021 issue of *Anesthesiology* similarly repeats the conclusions of both the Hussain Article and Ilfeld Review, further disseminating the false and misleading information contained in these articles. Compl. ¶ 35.

* * *

While the February 2021 issue of *Anesthesiology*, and accompanying materials, purported to present scientific conclusions which Defendants claim are immune from liability, Pacira has alleged that these conclusions were based on false objective statements of fact relating to the data and studies underlying the articles. Defendants have represented that their studies cover the relevant data sets on EXPAREL's effectiveness, when in fact they do not. Defendants have used this

distorted picture of the literature to draw false, pre-determined conclusions about whether EXPAREL really works.

In short, because these statements are based on verifiable facts, Pacira has sufficiently alleged actionable false statements. *See Wolfe*, 2017 WL 3977920, at *3; *Intervet, Inc. v. Mileutis, Ltd.*, 2016 WL 740267, at *7 (D.N.J. Feb. 24, 2016) (counterclaim allegation that plaintiff "communicated 'false information about the efficacy of Mileutis's Technology' … is sufficient at this stage of the litigation to plead this element of its trade libel counterclaim" (citation omitted)).

III. PACIRA HAS SUFFICIENTLY ALLEGED ALL OTHER ELEMENTS OF TRADE LIBEL

Defendants only half-heartedly contest that Pacira has alleged actual malice and special damages, and they do not dispute the publication element at all.[7] But Defendants' arguments regarding actual malice and damages focus on what Pacira will ultimately have to show to succeed on its claim, not what is sufficient for this

[7] *Anesthesiology* is available in both print and online forms, and the three articles Pacira challenged were published in both forms. Compl. ¶ 30. The challenged CME and podcast materials are likewise available online to those with a subscription. Compl. ¶¶ 59, 65. There can be no doubt that the challenged statements, by virtue of being published in print and online, were sufficiently communicated to a third person to satisfy the publication element. *Intervet*, 2016 WL 740267, at *7 (allegation that statement was communicated to a third person was sufficient to allege publication); *Mayflower Transit*, 314 F. Supp. 2d at 378 (statements published online satisfied publication requirement).

stage of the litigation. As explained below, Pacira has sufficiently alleged the other elements of its trade libel claim to survive a motion to dismiss.

A. Pacira Has Sufficiently Pleaded Actual Malice

Defendants claim that Pacira has failed to plead actual malice, arguing that Pacira's statements are merely conclusory, and that Pacira failed to prove that Defendants knowingly or recklessly made false statements about EXPAREL. Mot. at 24-28. "Actual malice means that the speaker 'knew the statement to be false or acted in reckless disregard of its truth or falsity.'" *Innovasystems, Inc. v. Proveris Sci. Corp.*, 2014 WL 3887746, at *4 (D.N.J. Aug. 6, 2014) (citation omitted); *Lynch v. N.J. Educ. Ass'n*, 735 A.2d 1129, 1135 (N.J. 1999). A finding of actual malice is appropriate where the defendant had "obvious reasons to doubt the veracity of the informat[ion]" published. *St. Amant v. Thompson*, 390 U.S. 727, 732 (1968). While a failure to investigate sources or a departure from industry standards is not, alone, sufficient to prove actual malice, "a plaintiff is entitled to prove the defendant's state of mind through circumstantial evidence … and it cannot be said that evidence concerning motive or care never bears any relation to the actual malice inquiry." *Moore v. Vislosky*, 240 F. App'x 457, 468 (3d Cir. 2007) (quoting *Harte-Hanks Commc'ns, Inc. v. Connaughton*, 491 U.S. 657, 668 (1989)). Actual malice may be inferred from evidence of "negligence, motive, and intent such that an accumulation of the evidence and appropriate inferences supports the existence of actual malice."

Schiavone Constr. Co. v. Time, Inc., 847 F.2d 1069, 1090 n.35 (3d Cir. 1988) (denying motion for summary judgment on actual malice).

Pacira does not have to prove its claim at this stage—it merely has to "plead facts from which malice might reasonably be inferred." *Innovasystems*, 2014 WL 3887746, at *4. Because "the question of actual malice entails a subjective inquiry into the defendant's belief as to the trustworthiness of the statements at issue," "[t]he finder of fact must determine whether the publication was indeed made in good faith." *Mzamane v. Winfrey*, 693 F. Supp. 2d 442, 505 (E.D. Pa. 2010) (citing *St. Amant*, 390 U.S. at 732). Malice may be alleged generally, because a party's state of mind often cannot be demonstrated directly. *Churchill Downs, Inc. v. NLR Entm't, LLC*, 2015 WL 5854134, at *8 (D.N.J. Oct. 5, 2015).

Pacira has more than cleared this low bar. Pacira has not simply made conclusory allegations that Defendants knew their statements were false and misleading. *See* Mot. at 25. Pacira has alleged—at length—in its complaint that Defendants' studies departed from accepted scientific and ethical standards in a multitude of ways that were so obvious, it suggests Defendants deliberately disregarded these standards in order to reach a predetermined outcome. Compl. ¶¶ 46, 49-53, 57, 62-64.

Pacira alleged, for example, that the authors of the Hussain Article deliberately failed to follow their own selection criteria in determining which studies

to include in their meta-analysis, resulting in the exclusion of studies favorable to EXPAREL. *Id.* ¶¶ 41, 46. The authors chose to use multiple widely-rejected methodologies, strongly suggesting a deliberate effort to arrive at a pre-determined outcome. *Id.* ¶¶ 42-46; *see supra* pp. 20-24. Indeed, the authors' conclusion that EXPAREL is "not superior" is belied by their own data, which shows that EXPAREL *was* superior to local anesthetics to a statistically significant degree. Hussain Article at 1.

With respect to the Ilfeld Review, Pacira likewise alleged that this article intentionally cherry-picked studies—among other things, failing to include the most relevant anesthesia procedure (direct infiltration of EXPAREL vs. a continuous infiltration of bupivacaine) in its analysis. Compl. ¶ 47. It is difficult to conceive how the authors could have omitted this comparison, except by design. More generally, the article excludes studies favorable to EXPAREL for seemingly superficial reasons, but hides the limitations of the studies that *were* included. *Id.* Pacira further alleged that Defendants Ilfeld and Gabriel failed to disclose financial payments they had received from Pacira's competitors, in violation of medical ethics. *Id.* ¶¶ 49-53. That they had previously made these disclosures elsewhere but did not do so here again evidences actual malice.

Pacira also alleged that the McCann editorial was specifically solicited by the editors of *Anesthesiology*, and that the editors of *Anesthesiology* did not solicit

commentary regarding EXPAREL from anyone else in advance of publishing the February 2021 issue. *Id.* ¶ 57. Why McCann's editorial was solicited was not disclosed, but the editors of *Anesthesiology* presumably wanted to throw the weight of McCann's background as the former acting Chair for the FDA Anesthetic and Analgesic Drug Products Advisory Committee behind the distorted Ilfeld and Hussain article conclusions. *Id.* Similarly, Pacira alleged that the CME activity was specifically crafted to convey a negative view about EXPAREL, consistent with Kharasch and the authors' biases. *Id.* ¶¶ 59-64. In the process, Defendants violated several ethical standards promulgated by the Accreditation Council for Continuing Medical Education. *Id.* Defendants then further disseminated the false and biased statements about EXPAREL through the podcast materials. *Id.* ¶¶ 65-67.

One possible explanation for this multitude of errors, of course, is that they are inadvertent: that ASA and the individual defendants are simply incompetent scientists. That appears to be what Defendants want this Court to believe. Another possible explanation, however, is that these errors were deliberate: that Defendants deliberately crafted the challenged articles and materials in order to reach a predetermined outcome that would disparage EXPAREL, consistent with their own financial interests and pro-opioid biases. *See Harte-Hanks*, 491 U.S. at 667-68 (evidence that newspaper had departed from accepted standards and evidence of motive were "supportive" of the lower court's finding of actual malice); *Schiavone*,

847 F.2d at 1090 n.35. "Where the defendant finds internal inconsistencies or apparently reliable information that contradicts its libelous assertions, but nevertheless publishes those statements anyway, the *New York Times* actual malice test can be met." *Schiavone*, 847 F.2d at 1091.

Viewing the facts in the light most favorable to Pacira, as the Court must, it is, at minimum, plausible that Defendants were aware of the errors and misstatements in the published articles, but proceeded with publication anyway for their own financial gain. *See Wolfe*, 2017 WL 3977920, at *3 (denying defendant's motion for summary judgment, because "a reasonable factfinder could conclude that Gooding was aware that 001 may be authentic but that it nonetheless declared that 002 was the only remaining *Competizione* so that Gooding could achieve the highest possible auction price"). One error may be inadvertent; multiple errors on this scale, and in violation of multiple industry standards, are not likely to be. At best, the evidence Pacira has alleged suggests that Defendants crafted their data in order to purposefully avoid information that contradicted their false statements about EXPAREL. *See Harte-Hanks*, 491 U.S. at 692 (newspaper's failure to interview a key witness was likely the "product of a deliberate decision not to acquire knowledge of facts that might confirm the probable falsity" of published statements); *Medure v. N.Y. Times Co.*, 60 F. Supp. 2d 477, 487 (W.D. Pa. 1999) (noting that a defendant's "purposeful avoidance of the truth may be evidence of actual malice").

Defendants claim that the articles were subject to peer-review, seeming to suggest that this immunizes the publications from any potential research misconduct. But whether and what kind of peer-review actually took place with these articles is a factual question that Pacira should be permitted to investigate in discovery. Moreover, the editor-in-chief of *Anesthesiology*, Dr. Kharasch, has recognized in his own publications that research misconduct can and does occur in peer-reviewed journals. Evan D. Kharasch et al., *Errors and Integrity in Seeking and Reporting Apparent Research Misconduct*, 127 Anesthesiology 733, 733-34 (Nov. 2017)[8]; Dkt. 58-7, Evan D. Kharasch et al., *Peer Review Matters: Research Quality and the Public Trust*, 134 Anesthesiology 1-3 (Jan. 2021)[9]. That is even more likely where, as here, the Editor-in-Chief of the journal in question, with final say over the content, has an undisclosed financial stake in promoting a particular view of the research at issue. Compl. ¶¶ 31-33, 69; *supra* pp. 11-13.

Either way, whether the challenged statements were "made with knowledge or reckless disregard for its truth is a material issue of fact" that cannot be resolved at the pleading stage. *See Wolfe*, 2017 WL 3977920, at *3; *see also St. Amant*, 390 U.S. at 732; *Schiavone*, 847 F.2d at 1093. Pacira's allegations related to actual malice are more than sufficient for this stage of the litigation. *See Floorgraphics,*

[8] https://doi.org/10.1097/ALN.0000000000001875.

[9] https://doi.org/10.1097/ALN.0000000000003608.

Inc. v. News Am. Mktg. In-Store Servs., Inc., 2006 WL 2846268, at *6 (D.N.J. Sept. 29, 2006) (finding malice sufficiently alleged where plaintiff "clearly and repeatedly alleges in the Complaint that Defendant 'intentionally' made false statements").

B. Pacira Has Sufficiently Pleaded Special Damages

Finally, Defendants claim that Pacira has failed to adequately plead special damages because Pacira failed to name specific customers who dropped Pacira's product as a result of the disparaging materials. Mot. at 28-30. This is wrong as a matter of law and fact.

As a matter of law, while Pacira will ultimately have to show "pecuniary loss that has been realized or liquidated, such as lost sales, or the loss of prospective contracts with customers," *Patel*, 848 A.2d at 835, courts do not necessarily require plaintiffs to allege the names of specific customers lost *at the pleading stage*. *See Graco, Inc. v. PMC Glob., Inc.*, 2009 WL 904010, at *33-35 (D.N.J. Mar. 31, 2009) (finding that complaint adequately pled special damages where complaint alleged that plaintiff "lost sales to established customers, existing distributors dropped its product lines, and it was prevented from acquiring new customers that were also recipients" of the disparaging publications); *Pactiv Corp. v. Perk-Up, Inc.*, 2009 WL 2568105, at *11 (D.N.J. Aug. 18, 2009) (similar); *cf. Intervet*, 2016 WL 740267, at *6 (defendant's counterclaim allegations were insufficient where defendant merely

stated generally that "as a direct and proximate result[] of the trade libel … [defendant] has incurred and will continue to suffer damages").

Defendants' argument is also factually incorrect. Pacira has identified specific instances of loss. It specifically alleged that in the weeks following the release of the articles, multiple existing customers reached out to Pacira to say they had seen the February 2021 issue of *Anesthesiology* and read at least one of the disparaging articles. Compl. ¶ 70. Pacira further alleged that several customers had informed it that, as a result of the articles, they will "either discontinue their use of Pacira's product EXPAREL, or are considering discontinuing use of it." *Id.* Pacira identified specific customers in a declaration filed concurrently with the complaint. Sherrod Decl. ¶¶ 2-3. These allegations are sufficient at this stage. *See Graco*, 2009 WL 904010, at *33-35.

Finally, Defendants suggest that Pacira is lying either to this Court or its investors because it has alleged damages in this case, but also reported to investors that the company is doing well. *See* Mot. at 29-30.[10] There is nothing inconsistent

[10] *See also* Press Release, ASA, Defending Science and the First Amendment, ASA Asks Federal Judge to Dismiss Pacira's Lawsuit (June 14, 2021), https://www.asahq.org/about-asa/newsroom/news-releases/2021/06/defending-science-and-the-first-amendment (stating that Pacira is "lying either to a federal judge or its investors"); Pat Anson, *Did Pacira Lie to Investors or a Federal Judge?*, Pain News Network (June 15, 2021), https://www.painnewsnetwork.org/stories/2021/6/15/did-pacira-lie-to-a-federal-judge-and-its-investors (reporting on press release and repeating Defendants' allegation).

in Pacira seeking damages for lost business even though, fortunately, the company continues to do well despite Defendants' best efforts. The law does not require libelous statements to be ruinous before a plaintiff may bring a trade libel claim. Aside from the jurisdictional amount required to establish this Court's diversity jurisdiction, there is no specific amount of loss that Pacira must suffer in order to bring its claim, as long as it *has* realized some loss. Defendants' accusation, without a shred of proof, that Pacira is misleading either its investors or this Court is therefore inappropriate, wholly uncalled for, and is itself a damaging and disparaging statement.

IV. AT MINIMUM, PACIRA SHOULD BE AFFORDED LEAVE TO REPLEAD

Pacira has done more than enough to meet its burden to plead facts which, if proven true, would state a claim. But should this Court disagree, Pacira should be afforded leave to amend its complaint. It is well-established that parties should be freely afforded leave to amend their pleadings even "following a dismissal in almost all circumstances simply by requesting such leave from the court." *United States v. Union Corp.*, 194 F.R.D. 223, 235 (E.D. Pa. 2000); *see also Foglia v. Renal Ventures Mgmt., LLC*, 830 F. Supp. 2d 8, 23 (D.N.J. 2011) (leave to amend should be freely given unless inequitable or futile).

Here, Pacira has already developed substantial additional support for its claims, including by obtaining detailed statements from relevant experts explaining

why Defendants' disparaging statements are inaccurate and represent significant and inexplicable departures from established scientific norms.[11] *See, e.g.*, Dkts. 3-3 to 3-8. Even assuming the Complaint is insufficient, the Complaint coupled with these additional materials put Defendants on notice of Pacira's claims. As such, should this Court disagree with Pacira that it has stated a claim on which relief may be granted, it should be afforded the opportunity to address any deficiency by amendment.

CONCLUSION

For the foregoing reasons, Pacira has alleged each element of its trade libel claim, and respectfully requests that this court deny Defendants' motion to dismiss. In the alternative, should the Court find that Pacira's allegations are not sufficient, Pacira should be given leave to amend its complaint to add additional detail to support its allegations.

[11] Pacira submitted these materials in connection with its motion for a preliminary injunction. It later withdrew that motion after Defendants indicated their preference for expedited discovery, and Pacira proposed that the parties quickly proceed to expedited discovery and resolution of the merits of this case. Of course, Defendants have now reversed course and sought to preclude discovery altogether.

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Respectfully submitted,

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